

**Notice of Allowability**

Application No.

10/591,993

Applicant(s)

KANAZAWA ET AL.

Examiner

SCOTT LONG

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/13/2009.
2. ☒ The allowed claim(s) is/are 1.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>20091205</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|  | 9. <input type="checkbox"/> Other _____.   |

/SCOTT LONG/  
Examiner, Art Unit 1633

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/2009 has been entered.

***Priority***

This application claims benefit from PCT/JP2005/04007 (filed 8 March 2005). This application also claims benefit from foreign application, JAPAN 2004-066218 (filed 9 March, 2004). The instant application has been granted the benefit date, 9 March 2004, from the foreign application, JAPAN 2004-066218.

***RESPONSE TO ARGUMENTS***

***35 USC § 103***

The rejection of claims 1 and 5 under 35 U.S.C. 103(a) as being unpatentable over Harton et al. (Molecular and Cellular Biology, Sept. 2000; 20(17):6185-6194) in view of Lindqvist et al. (Trends in Genetics. 2002; S7-S13) and further in view of Otten et al. (Journal of Immunology. 2003; 170: 1150-1157) is withdrawn in response to the applicants arguments and/or claim amendments. The applicant's claim amendments and arguments have been fully considered and are persuasive. The applicant has

Art Unit: 1633

amended the claims. In addition, the examiner has provided an examiner's amendment to join the phenotype limitations from claim 5 to the structural limitations of the claimed transgenic animal of claim 1. As amended claim 1 is not taught or suggested by the cited art, the claimed transgenic mouse or rat is non-obvious. Therefore, the examiner hereby withdraws the rejection of claims 1 and 5 under 35 U.S.C. 103(a) as being unpatentable over Harton et al. in view of Lindqvist et al. and further in view of Otten et al.

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Armstrong on 12/8/2009.

The claims have been amended as follows:

1. (Amended) A transgenic mouse or rat ~~comprising~~ whose genome comprises a foreign DNA, the foreign DNA ~~further~~ comprising a type II collagen promoter, a DNA selected from the group consisting of MHC class II transactivator gene, ~~an active region of the MHC class II transactivator gene, and a mutant MCH class II transactivator gene,~~ said mutant having a master switch function for controlling an expression of the MHC

Art Unit: 1633

~~class II genes, and a type II collagen~~ an enhancer sequence for activating transcription of the ~~class II transactivator gene with an origin of the enhancer being the same as that of the type II collagen promoter~~, wherein said DNA is located under the control of said type II collagen promoter and enhancer, wherein administration of type II collagen to said transgenic mouse or rat at a dose of 0.01 mg to 0.05 mg two or more times results in presentation of pathologic conditions of human rheumatoid arthritis in said transgenic mouse or rat, wherein the pathologic conditions of human rheumatoid arthritis show the following pathologic conditions (1) to (6):

- (1) Joint swelling is observed in the whole body;
- (2) Joint swelling lasting for a week or more is observed;
- (3) Destruction, ankylosis, or deformity of bones in the extremities is observed;
- (4) Infiltration of lymphoid cells is observed;
- (5) Cartilage destruction and bone destruction due to formation of granulation tissue are observed; and
- (6) Joint deformity progresses through early stage (stage I) and moderate stage (stage II).

Claim 2-17. (Canceled).

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The prosecution history provides evidence for allowability.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Claim 1 is allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/  
Patent Examiner, Art Unit 1633